Medication safety in Vietnamese hospitals

Nguyen, Huong

Chapter 4

Errors in preparation and administration of insulin in two urban Vietnamese hospitals: An observational study

Nguyen HT, Nguyen TD, Haaijer-Ruskamp FM, Taxis K

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Abstract

Background: Medication errors involving insulin are common, particularly during the administration stage, and may cause severe harm. Little is known about the prevalence of insulin administration errors in hospitals, especially in resource-restricted settings, where the burden of diabetes is growing alarmingly.

Objectives: The aim of this study was to determine the prevalence, type and potential clinical outcome of errors in preparation and administration of insulin in resource-restricted setting hospitals.

Methods: This study was conducted on six wards in two urban public hospitals in Vietnam using a direct observation method. Details of insulin preparation and administration were collected by pharmacy students 12 hours per day on 7 consecutive days on each ward. Potential clinical outcome was judged by a panel of four experts using a validated scale.

Results: The error rate was 28.8% (95% confidence interval 23.1%–35.2%, n = 66 out of 229 insulin doses), all with potentially moderate/severe outcome. Higher error rates were observed for infusion doses than for subcutaneous ones (80.0% vs. 22.5%, $p < 0.01$). Incorrect time, incorrect preparation/administration technique, and omissions were mostly encountered.

Discussion: Interventions suitable for resource-restricted settings need to be developed and tested to improve insulin preparation and administration, probably starting with education and providing information, especially infusion doses.

Keywords: diabetes mellitus, insulin, medication errors, nursing care, Vietnam

Introduction

Medication errors involving insulin are common and may cause severe harms or even death (National Patient Safety Agency 2010b). It has been reported that about one third of fatal medical errors are related to insulin therapy (Anonymous 2005). Insulin-related errors were more frequently observed during the administration stage (61%) compared with prescribing (17%) and dispensing (10%; Cousins *et al.* 2011). Errors are clinically important because insulin requires accurate dosing and timely administration as well as careful monitoring (Walden 2010). So far, most evidence of insulin-related errors is from national incident reporting systems from developed countries. Omitted, delayed, incorrect insulin product, and incorrect dose were the most common insulin-related adverse drug events (Cousins *et al.* 2011; Pennsylvania Patient Safety Advisory 2010). Omitted or delayed doses expose patients to longer periods of unanticipated hyperglycemia and could have serious consequences (National Patient Safety Agency 2010a). An incorrect dose or incorrect insulin product could lead to hypoglycemia or hyperglycemia (Cousins *et al.* 2011).

Although time consuming, direct observation of medication preparation and administration is considered the "gold standard" method to investigate the prevalence and type of medication administration errors (Flynn *et al.* 2002). A recent review article showed that there are a considerable number of observation-based studies on medication administration errors in hospitals (Keers *et al.* 2013), but little knowledge specifically about insulin errors. Studies are particularly needed from resource-restricted settings, that is, developing and transitional countries, where the burden of diabetes is growing alarmingly. In such countries, attention for patient safety is insufficient because of poor health system infrastructure and inadequately trained healthcare staff (Wilson *et al.* 2012).

In Vietnam, it is estimated that 2.5% of people older than age 20 years experience diabetes mellitus type 2 (Beran 2008). The number of diabetes cases is expected to double in the next 20 years (Shaw *et al.* 2010). In general, diabetes care is not standardized, and currently, there is no national treatment guideline. Patients with diabetes are treated at home with oral glucose lowering medications and/or insulin and have regular checkups in hospital outpatient clinics. They should be admitted to the hospital if they are having uncontrolled high blood glucose, complications, or comorbidities. Those patients may need to use insulin as an additional treatment, to switch from oral medications to insulin or to increase the insulin dose depending on the patient's condition. Between 10% and 33% of hospitalized patients with diabetes were reported to use insulin (Beran 2008). In Vietnam, insulin is available in various types such as rapid-, short-, intermedi-

ate-, and long-acting insulin (Beran 2008). In this study, the aim is to determine the prevalence, type, and potential clinical outcome of errors in preparation and administration of insulin in hospitals.

Methods

Setting

The study was conducted in two large public hospitals in a large city in Vietnam. Both are provincial general hospitals: hospital A has 700 beds, and hospital B has 1000 beds. In each hospital, an intensive care unit and a postsurgery ward were studied. In hospital A, one general internal medicine was studied, and in hospital B, one trauma unit was studied. Insulin doses were indicated by doctors and written in the patients' medical records. Nurses transcribed prescriptions, including insulin, either manually on inpatient drug charts (paper, hospital A) or entered them into the patients' electronic drug use records in a computer and printed out the drug regimen for each patient (hospital B). Nurses prepared and administered medications referring to these charts. Every medication administration on the ward was recorded in the nurse chart. Most nurses held an Associate's Degree in Nursing. In each shift, each nurse was assigned three to six patients. Clinical pharmacists were not available at ward level. Commonly used insulins were stored in refrigerators on the wards.

Data collection

Data were collected between March and June 2011 – 12 hours per day for 7 consecutive days on each ward – by four pharmacy students using the direct observation method (Dean & Barber 2001). The students were trained for about a week through lectures and ward-based observations by a senior researcher to ensure all observers used the same definition of an error. Agreement between observers was not performed. A 1-day pilot observation was conducted on each study ward – before the main study – to help the observers get familiar with the study wards. This also helped nursing staff get comfortable with the presence of observ-

ers (Allan & Barker 1990). The observers followed the nurses during preparation and administration and recorded all details of insulin doses. For ethical reasons, the observers intervened in case they were aware of a severe error reaching the patient (e.g., giving an unordered dose to a patient). These errors were also included in the analysis. Nurses were asked for permission to observe – but were not informed about the true purposes of the study – to minimize any bias, which might be caused by being observed. They were told that the observer was a pharmacy student who wanted to learn more about ward-based drug preparation and administration. Results were reported to the nurses after completion of the study. A follow-up educational intervention was designed (Nguyen *et al.* 2014).

Medication errors were defined as deviations in drug preparation and administration from the doctors' prescriptions, the hospital policies and procedures, or the manufacturers' instructions (Chedoe *et al.* 2012). Medication errors were classified into nine categories: incorrect drug, incorrect dose, incorrect dosage form, deteriorated drug, incorrect preparation technique, omission, unordered drug, incorrect time (including early and delayed), and incorrect administration technique (including incorrect route and incorrect administration rate; Table 1; (American Society of Hospital Pharmacists 1993; Barker *et al.* 2002; Wirtz *et al.* 2003). Potential clinical outcome of a dose with error(s) was judged by four experts (one doctor, one nurse, and two pharmacists) – who had at least 5 years working experience in the hospitals – using a validated scale between 0 (labeled as *no harm*) and 10 (*death*). A mean score below 3 suggested minor outcome, between 3 and 7 suggested a moderate outcome, and above 7 suggested a severe outcome (Chedoe *et al.* 2012).

The study was approved by the medical ethics committee and the management board of the study hospitals.

Table 1. Types of medication errors

Error	Definition
Incorrect drug	Preparation of a drug that differs from the prescribed one.
Incorrect dose	Preparation of a dose that is higher than, or less than, the amount prescribed (± 10%).
Incorrect dosage form	Formulation of drug deviates from the one prescribed.
Deteriorated drug	Preparation of a drug that has expired or for which the physical or chemical dosage-form integrity has been compromised.
Incorrect preparation technique	Inappropriate procedure or improper technique in the preparation of a drug (compared with manufacture's instruction or hospital policy, including wrong diluent, wrong solvent, wrong volume, and possible incompatibility).
Omission	Failure to administer an ordered dose to a patient.
Unordered drug	Administration to the patient of nonprescribed medication.
Incorrect time	Administration to the patient of a medication at a different time from the prescribed or predefined time including early (less than -1 hour) and delayed (greater than +1 hour) doses.
Incorrect administration technique	Inappropriate procedure or improper technique in the administration of a drug (rate, incompatibility, route, dose [± 10%] if preparation with correct dose). A rate error was identified if the administration took less than 3 or more than 5 minutes (for a bolus dose) or 15% shorter/longer than the period that the medication was supposed to be infused (for an infusion dose). An incompatible error was determined if there was incompatible information available in at least one of three documents including Handbook on Injectable Drugs 15th edition (Trissel 2009), AHFS Drug Information (McEvoy *et al.* 2009), and manufacturers' instructions.

Data analysis

Descriptive analysis was performed using SPSS statistical package (SPSS 20.0, SPSS Inc., IBM Corporation, Somers, NY). The overall error rate (with 95% confidence interval) was calculated by dividing the number of doses with one or more errors (i.e., erroneous doses) by the sum of given doses plus omitted doses, then multiplying it by 100. The rate of each error type was calculated by dividing the number of errors of that particular type by the sum of given doses plus omitted doses, then multiplying it by 100. Differences in error rates between infusion and subcutaneous doses were tested by chi-square test. Significant level was set at $p < 0.05$.

Results

Table 2. Error frequencies and examples

Error	n	%a	Example
Incorrect drug	1	0.4	A dose of 20 IU of short-acting insulin was given instead of 20 IU of combined insulin (short- and long-acting insulin).
Incorrect dose	1	0.4	A dose of 15 IU of combined insulin was given instead of 25 IU as prescribed.
Incorrect dosage form	0	0.0	
Deteriorated drug	0	0.0	
Incorrect preparation technique	17	7.4	A dose of 5 IU of short-acting insulin and 10 mL of KCl 10% was prepared with 500 mL of NaCl 0.9%/glucose 5% instead of 500 mL of NaCl 0.9% as prescribed. The nurse did not mix the solution sufficiently when preparing the medication.
Omission	6	2.6	A dose of 10 IU of combined insulin was omitted.
Unordered drug	2	0.9	A patient received an infusion dose of 5 IU of short-acting insulin and KCl 10% 10 mL in 500 mL of glucose 5%, which were prescribed for another patient.
Incorrect time: early (less than -1 hour)	17	7.4	A dose of 10 IU of combined insulin was given to patient at 1 pm instead of 4 pm as prescribed.
Incorrect time: delayed (greater than +1 hour)	24	10.5	A patient was prescribed combined insulin of 10 IU twice a day (8 am and 6 pm). The morning dose was given 2 hours late; the evening dose was given on time.
Incorrect administration technique	7	3.1	A dose of 5 IU of short-acting insulin and 10 mL of KCl 10% in 500mL of NaCl 0.9%/glucose 5% was given in 5 hours instead of 8 hours and 30 minutes as prescribed.

Note. There were 75 errors in 66 of 229 insulin doses. IU = International Unit.

a Rate as a percent of 229 insulin doses.

Overall, 229 insulin doses (204 subcutaneous and 25 infusions) were included. Of which, 66 doses had at least one error, that is, an error rate of 28.8% (95% confidence interval 23.1%–35.2%). Fifty-eight doses (23.5%) were judged to have potentially moderate outcome, and eight doses (3.5%) were judged to have potentially severe outcome. Higher error rates were observed for infusion doses than for subcutaneous ones (80.0% vs. 22.5%, $p < 0.01$). Seven doses involved two errors, and one involved three errors; so in total, 75 errors were identified. More than half of all errors were incorrect time errors (54.7%), followed by incorrect preparation technique (22.7%), incorrect administration technique (9.3%), and omission (8.0%). There were no incorrect dosage forms or deteriorated drug errors (Table 2).

Discussion

Errors occurred in about one third of all insulin doses with omitted, delayed, incorrect drug and incorrect dose being the most frequent. This is in line with studies of insulin-related adverse drug events in the United Kingdom and in the United States (Cousins *et al.* 2011; Pennsylvania Patient Safety Advisory 2010). Omitted or delayed doses (encountered in 40% of all errors) expose patients to longer periods of unanticipated hyperglycemia and could have serious consequences (National Patient Safety Agency 2010a). An incorrect dose or incorrect drug (insulin product) could lead to hypoglycemia or hyperglycemia (Cousins *et al.* 2011). A high number of doses given too early – even 3 hours earlier than the scheduled time – was also observed. This could lead to hypoglycemia, which may have severe consequences, such as confusion, fainting or even seizures, coma, and death. Particularly high error rates were associated with infusions (80.0%), mainly preparation and administration technique errors. This is not surprising as infusions require more manipulations than subcutaneous doses. Hence, there were more opportunities for errors in infusions.

Education is probably the first feasible step to achieve improvements (Chedoe *et al.* 2012). Providing posters at work stations and on insulin-storing refrigerators and attaching alert stickers to insulin products were successful to reduce fatal insulin dosing errors (Dooley *et al.* 2011). A broad range of other suggestions have been published but not formally evaluated. This includes providing wards with guidelines emphasizing potential insulin-related errors and highlighting the danger of such errors, particularly omitted and delayed doses (National Patient Safety Agency 2010a). Using insulin passports – small booklets providing patient information and records of the patient's current insulin products (National Patient Safety Agency 2011) – and/or having dedicated nurses (or diabetes specialist team) responsible for insulin (Walden 2010) has been recommended for reducing errors, such as incorrect insulin product, incorrect dose, and omitted/unordered doses. Other recommendations include having nurses double check medication, making use of centralized preparation of doses in the pharmacy department, changing the supply system to ensure timely medicine supply, and making policies to promote safety culture (National Patient Safety Agency 2010a; Grissinger 2003). Technological interventions, such as electronic prescribing, barcoded administration, and the use of smart pumps, may also be powerful to prevent incorrect drug, incorrect dose, unordered drug, and rate errors (Pham *et al.* 2012; Lemoine & Hurst 2012). But such solutions are not feasible in a resource-restricted

setting. In practice, successful implementation of quality improvement strategies needs a multidisciplinary team with strong leadership endorsed by hospital managers (Hughes 2008).

As in other observation-based studies (Keers *et al.* 2013), information about the actual harms of errors were not collected. However, the error rate was high, and all erroneous doses were considered having potentially clinically moderate or severe outcomes. This may be because of the constraints of the resource-restricted setting, such as poor health system infrastructure and inadequately trained healthcare staff (Wilson *et al.* 2012). Errors are preventable, so any harm arising from these incidents is too much. This suggested an urgent need of feasible strategies to improve insulin preparation and administration. Cost-effective interventions suitable for resource-restricted settings need to be developed and tested, probably starting with education and providing information.

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Conflict of interest

The authors have no conflicts of interest to disclose.

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